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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,350	09/18/2000	Avi Ashkenazi	10466/14	8200

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/25/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/665,350

Applicant(s)

ASHKENAZI ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-47 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-47 and 49-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 39-44 have been amended and claim 48 has been cancelled as requested in the amendment of Paper No. 21, filed on June 06, 2003. Claims 39-47 and 49-51 are pending in the instant application.

Claims 39-47 and 49-51 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on June 06, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Specification***

5. The instant specification stands objected to for reasons of record in section 6 of Paper No. 19. Specifically, because capital letters in Tables 1-5 are less than .21 cm, the instant specification is not in compliance with 37 C.F.R. 1.52 (b). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

6. Claims 39-47 and 49-51 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in section 7 of Paper No. 19. Briefly, the instant application has

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provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

In Response Applicant submits the summary of the Utility Guidelines and related case law and further traverses the rejection on the premises that Example 92 of the instant specification provides support for patentable utility for the instant claimed PRO187 (section 7 of the Response). Applicant argues that because the instant specification discloses 2-8 fold amplification of genomic PRO 187 DNA sequences in colon and lung cancer samples (cell lines and primary tumors), then the instant claimed PRO187 polypeptides can be used as a lung and colon tumor markers. These arguments were fully considered but are not deemed to be persuasive for the reasons that follow.

The data regarding significant amplification of DNA sequences encoding PRO187 of the instant invention in lung and colon tumors supports the utility of the instant DNA only. One skilled in the art readily understands that because the specific sequences encoding PRO187 are amplified in tumor tissues compare to aneuploid and normal controls, then these sequences could be used as markers for lung and colon carcinomas, which substantiates for a specific and substantial credible utility of DNA encoding PRO187. However, the increased copy of DNA does not provide a readily apparent use for the polypeptide PRO 187 itself, for which there is no information regarding level of expression, specific biological activity or role in cancer disclosed. Moreover, the art clearly teaches that amplification of a gene is not related to the expression of a protein encoded by that particular gene (see Konopka et al., 1986, the abstract, for example).

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The Declaration of Goddard under 37 CFR 1.132 filed June 06, 2003 is insufficient to overcome the rejection of the instant claims because it addresses the validity of TaqMan PCR assay as an amplification assay utilizing genomic DNA samples, which was never disputed or doubted by the Examiner.

Since the instant specification does not disclose a credible "real world" use for the encoded protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

***Claim Rejections - 35 USC § 112***

7. Claims 39-47 and 49-51 stand rejected under 35 U.S.C. 112, first paragraph for reasons of record in section 8 of Paper No. 19. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 39-43, as amended, stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in section 9 of Paper No. 19.

Applicant submits that because the claims now include recitation regarding association of the instant polypeptides with lung and colon tumors, the instant claims now satisfy the written description requirement. This argument has been fully considered but is not deemed to be persuasive because, as fully explained in the previous office action, the instant specification fails

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to describe the entire genus of the claimed polypeptides, which are 80%, 85%, 90%, 95% and 99% identical to an amino acid sequence having SEQ ID NO: 23 and are associated with formation of lung and colon tumors. There is no disclosure of complete structure of the claimed polypeptides, or other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure), or representative number of species for the claimed genus, except for one polypeptide of SEQ ID NO: 23. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. Claims 39-47 and 48-51 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record in sections 12 and 13 of paper No. 19. Specifically claims 39-44 in part (b) and 46 are vague and indefinite for recitation of "associated signal peptide" and claim 47 is indefinite for recitation "extracellular domain" claimed to be shown in Figure 11. Applicant submits that the claims were amended to delete the indefinite recitations (last section of the Response). However, it is clear that the claims, as amended, still recite "associated signal peptide" and "extracellular domain", and, therefore, the rejection is maintained. Claims 45 and 48-51 are indefinite for being dependent from indefinite claims.

### ***Conclusion***

10. No claim is allowed.

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11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

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28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
November 24, 2003

OC

  
JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800